

Claims:

1. A recognition molecule, **characterized in that** it comprises an amino acid sequence which contains
 - (i) the amino acid sequence SEQ ID NO. 1 and
 - (ii) the amino acid sequence SEQ ID NO. 2 or 3 and
 - (iii) the amino acid sequence SEQ ID NO. 4, 5 or 6 and specifically binds the core 1 antigen.
2. The recognition molecule according to claim 1, **characterized in that** it further comprises an amino acid sequence which contains
 - (i) the amino acid sequence SEQ ID NO. 7 or 8 or 9 and
 - (ii) the amino acid sequence SEQ ID NO. 10 or 11 and
 - (iii) the amino acid sequence SEQ ID NO. 12 or 13 and specifically binds the core 1 antigen.
3. The recognition molecule according to any of claims 1 or 2, **characterized in that** it is modified by mutation, deletion and/or insertion in at least one of sequences SEQ ID Nos. 1 to 13 and specifically binds the core 1 antigen.
4. The recognition molecule according to any of claims 1 to 3, **characterized in that** at least one amino acid in at least one sequence in accordance with SEQ ID Nos. 1 to 13 is replaced by an amino acid having analogous physicochemical properties, and that the recognition molecule specifically binds the core 1 antigen.
5. The recognition molecule according to any of claims 1 to 4, **characterized in that** the sequence SEQ ID NO. 1 is replaced by an equivalent canonical structure vari-

ant in accordance with SEQ ID Nos. 14 to 17 and/or at least one sequence of sequences SEQ ID NO. 2 or 3 is replaced by an equivalent canonical structure variant in accordance with SEQ ID Nos. 18 to 27 and/or at least one sequence in accordance with SEQ ID Nos. 7 to 9 is replaced by an equivalent canonical structure variant in accordance with SEQ ID Nos. 28 to 45 and the recognition molecule specifically binds the core 1 antigen.

6. The recognition molecule according to any of claims 1 to 5, **characterized in that** it comprises amino acid sequences having a homology of at least 60%, preferably 70%, more preferably 80%, especially preferably 90%, with respect to the sequences SEQ ID Nos. 1 to 13, said recognition molecule specifically binding the core 1 antigen.
7. The recognition molecule according to any of claims 1 to 6, **characterized in that** it further comprises framework sequences separating, enclosing and/or flanking said amino acid sequences.
8. The recognition molecule according to claim 7, **characterized in that** the framework sequences are selected from the group comprising the immunoglobulin superfamily, protease inhibitors, lectins, helix bundle proteins and/or lipocalins.
9. The recognition molecule according to claim 7 or 8, **characterized in that** the framework sequences are antibody framework sequences.
10. The recognition molecule according to claim 8 or 9, **characterized in that** the antibody framework sequences for the recognition molecule according to claim 1 are sequences of the variable heavy chain, V_H , and the anti-

body framework sequences for the additional sequences of the recognition molecule according to claim 2 are sequences of the variable light chain, V_L .

11. The recognition molecule according to claim 9 or 10, **characterized in that** the antibody framework sequences are of murine origin.
12. The recognition molecule according to claim 9 or 10, **characterized in that** the antibody framework sequences are of human origin.
13. The recognition molecule according to any of claims 9 to 12, **characterized in that** the antibody framework sequences are derived from framework sequences or combinations of framework sequences in accordance with claims 11 or 12.
14. The recognition molecule according to any of claims 8 to 13, **characterized in that** the antibody framework sequences
 - a) FRH1, FRH2, FRH3 and FRH4 for the variable heavy chain V_H are the following amino acid sequences, the amino acid position corresponding to the numbering according to Kabat:

| | |
|------------------------|-----------|
| for FRH1 in position 1 | Q or E |
| 2 | V |
| 3 | Q, K or T |
| 4 | L |
| 5 | K or V |
| 6 | E or Q |
| 7 | S |
| 8 | G |
| 9 | A |

- 101 -

| | |
|----------------------|--------------|
| 10 | E |
| 11 | L or V |
| 12 | V or K |
| 13 | R or K |
| 14 | P |
| 15 | G |
| 16 | T or A |
| 17 | S |
| 18 | V |
| 19 | K |
| 20 | I or V |
| 21 | S or P |
| 22 | C |
| 23 | K |
| 24 | A, V, S or T |
| 25 | S |
| 26 | G |
| 27 | Y, F, S or D |
| 28 | T |
| 29 | F, L or I |
| 30 | T |
| for FRH2 in position | 36 W |
| | 37 V |
| | 38 K or R |
| | 39 Q |
| | 40 R or A |
| | 41 P |
| | 42 G |
| | 43 H or Q |
| | 44 G |
| | 45 L |
| | 46 E |

| | |
|----------------------|-----------|
| 47 | W or R |
| 48 | I or M |
| 49 | G |
| for FRH3 in position | |
| 66 | K or R |
| 67 | A or V |
| 68 | T |
| 69 | L or M |
| 70 | T |
| 71 | A, L or T |
| 72 | D |
| 73 | T |
| 74 | S |
| 75 | S or T |
| 76 | S |
| 77 | T |
| 78 | A |
| 79 | Y |
| 80 | M |
| 81 | Q or E |
| 82 | L |
| 82a | S |
| 82b | S or R |
| 82c | L |
| 83 | T or R |
| 84 | S |
| 85 | E |
| 86 | D |
| 87 | S or T |
| 88 | A |
| 89 | V |
| 90 | Y |
| 91 | F or Y |

| | |
|----------------------|---------------|
| 92 | C |
| 93 | A |
| 94 | Y, K or R |
| for FRH4 in position | 103 W |
| | 104 G |
| | 105 Q |
| | 106 G |
| | 107 T |
| | 108 T, S or L |
| | 109 V or L |
| | 110 T |
| | 111 V |
| | 112 S |
| | 113 S or A |

- b) FRL1, FRL2, FRL3 and FRL4 for the variable light chain V_L are the following amino acid sequences, the amino acid position corresponding to the numbering according to Kabat:

| | |
|----------------------|-------------|
| for FRL1 in position | 1 D |
| | 2 I, V or L |
| | 3 Q or L |
| | 4 M |
| | 5 T |
| | 6 Q |
| | 7 T or S |
| | 8 P |
| | 9 L |
| | 10 S |
| | 11 L |
| | 12 P |
| | 13 V |

| | | |
|----------------------|----|--------|
| | 14 | S or T |
| | 15 | L or P |
| | 16 | G |
| | 17 | D or E |
| | 18 | Q or P |
| | 19 | A |
| | 20 | S |
| | 21 | I |
| | 22 | S |
| | 23 | C |
| for FRL2 in position | 35 | W |
| | 36 | Y |
| | 37 | L |
| | 38 | Q |
| | 39 | K |
| | 40 | P |
| | 41 | G |
| | 42 | Q |
| | 43 | S |
| | 44 | P |
| | 45 | K or Q |
| | 46 | L |
| | 47 | L |
| | 48 | I or V |
| | 49 | Y |
| for FRL3 in position | 57 | G |
| | 58 | V |
| | 59 | P |
| | 60 | D |
| | 61 | R |
| | 62 | F |
| | 63 | S |

| | |
|----------------------|--------|
| 64 | G |
| 65 | S |
| 66 | G |
| 67 | S |
| 68 | G |
| 69 | T |
| 70 | D |
| 71 | F |
| 72 | T |
| 73 | L |
| 74 | K |
| 75 | I |
| 76 | S |
| 77 | R |
| 78 | V |
| 79 | E |
| 80 | A |
| 81 | E |
| 82 | D |
| 83 | L or V |
| 84 | G |
| 85 | V |
| 86 | Y |
| 87 | Y |
| 88 | C |
| for FRL4 in position | |
| 98 | F |
| 99 | G |
| 100 | G or Q |
| 101 | G |
| 102 | T |
| 103 | K |
| 104 | L |

| | |
|------|--------|
| 105 | E |
| 106 | I or L |
| 106a | K |
| 107 | R |
| 108 | A |

15. The recognition molecule according to any of claims 1 to 14, **characterized in that** the recognition molecule comprises a sequence in accordance with SEQ ID Nos. 46 to 94.
16. The recognition molecule according to claim 15, **charac-
terized in that** the recognition molecule comprises a combination of sequences SEQ ID Nos. 46 and 80, or SEQ ID Nos. 47 and 81, or SEQ ID Nos. 48 and 80, or SEQ ID Nos. 50 and 80, or SEQ ID Nos. 53 and 82, or SEQ ID Nos. 52 and 83, or SEQ ID Nos. 55 and 83, or SEQ ID Nos. 54 and 80, or SEQ ID Nos. 51 and 83, or SEQ ID Nos. 49 and 80, or SEQ ID Nos. 56 and 90, or SEQ ID Nos. 57 and 90, or SEQ ID Nos. 57 and 86, or SEQ ID Nos. 58 and 87, or SEQ ID Nos. 56 and 91, or SEQ ID Nos. 59 and 91, or SEQ ID Nos. 60 and 87, or SEQ ID Nos. 61 and 90, or SEQ ID Nos. 56 and 88, or SEQ ID Nos. 56 and 85, or SEQ ID Nos. 59 and 90, or SEQ ID Nos. 62 and 90, or SEQ ID Nos. 59 and 86, or SEQ ID Nos. 74 and 92, or SEQ ID Nos. 63 and 87, or SEQ ID Nos. 74 and 87, or SEQ ID Nos. 74 and 89, or SEQ ID Nos. 74 and 85, or SEQ ID Nos. 64 and 86, or SEQ ID Nos. 74 and 86, or SEQ ID Nos. 63 and 86, or SEQ ID Nos. 65 and 85, or SEQ ID Nos. 65 and 86, or SEQ ID Nos. 66 and 85, or SEQ ID Nos. 67 and 87, or SEQ ID Nos. 68 and 86, or SEQ ID Nos. 72 and 88, or SEQ ID Nos. 69 and 90, or SEQ ID Nos. 70 and 90, or SEQ ID Nos. 69 and 92, or SEQ ID Nos. 73 and 86, or SEQ ID

Nos. 69 and 89, or SEQ ID Nos. 71 and 92, or SEQ ID Nos. 56 and 86, or SEQ ID Nos. 65 and 92.

17. The recognition molecule according to any of claims 1 to 16, **characterized in that** the variable heavy chain V_H and the variable light chain V_L are located on different polypeptide chains.
18. The recognition molecule according to any of claims 1 to 16, **characterized in that** the variable heavy chain V_H and the variable light chain V_L are directly linked to each other in a fusion protein.
19. The recognition molecule according to claim 18, **characterized in that** the chains in the fusion protein are linked via a linker.
20. The recognition molecule according to claim 19, **characterized in that** the linker consists of 1 to 9 amino acids.
21. The recognition molecule according to any of claims 1 to 20, **characterized in that** the recognition molecule comprises additional His-tag, myc-tag, high-lysine sequences and/or multimerization sequences.
22. The recognition molecule according to any of claims 1 to 21, **characterized in that** it is derived from an immunoglobulin.
23. The recognition molecule according to claim 22, **characterized in that** it is a single-chain antibody fragment, a multibody, a Fab fragment, a fusion protein of an antibody fragment with peptides or proteins and/or an immunoglobulin of the IgG, IgM, IgA, IgE, IgD isotypes and/or subclasses thereof.

24. The recognition molecule according to claim 23, **characterized in that** it is a murine, chimerized, humanized, human, partially human antibody or antibody fragment.
25. The recognition molecule according to claim 23, **characterized in that** it is an IgM without J chain.
26. The recognition molecule according to claim 23, **characterized in that** it comprises a sequence in accordance with SEQ ID Nos. 95 to 113.
27. A construct comprising the recognition molecules according to any of the claims 1 to 26, **characterized in that** the recognition molecules are fused, chemically coupled or non-covalently associated with accessory sequences and/or structures.
28. The construct according to claim 27, **characterized in that** the recognition molecules are fused, chemically coupled, covalently or non-covalently associated with (i) immunoglobulin domains of various species, (ii) enzyme molecules, (iii) interaction domains, (iv) domains for stabilization, (v) signal sequences, (vi) fluorescent dyes, (vii) toxins, (viii) catalytic antibodies, (ix) one or more antibodies or antibody fragments with different specificity, (x) cytolytic components, (xi) immunomodulators, (xii) immunoeffectors, (xiii) MHC class I or class II antigens, (xiv) chelating agents for radioactive labelling, (xv) radioisotopes, (xvi) liposomes, (xvii) transmembrane domains, (xviii) viruses and/or (xix) cells.
29. The construct according to claim 28, **characterized in that** the cells are macrophages.

30. An isolated nucleic acid molecule comprising nucleic acid sequences encoding the amino acid sequence of at least one recognition molecule according to claims 1 to 26 or a construct according to claims 27 to 29.
31. The nucleic acid molecule according to claim 30, **characterized in that** it is a genomic DNA, a cDNA and/or an RNA.
32. An expression cassette or vector comprising a nucleic acid molecule according to claim 30 or 31 and a promoter operatively linked with the nucleic acid.
33. A virus comprising at least one vector or expression cassette according to claim 32.
34. A host cell comprising at least one vector or expression cassette according to claim 32.
35. The host cell according to claim 34, **characterized in that** it is a prokaryotic or eukaryotic cell.
36. The host cell according to claim 35, **characterized in that** it is a bacterial, yeast, plant, insect and/or mammal cell.
37. The host cell according to claim 36, **characterized in that** the mammal cell is a hamster, mouse and/or human cell.
38. The host cell according to any of claims 34 to 37, **characterized in that** the host cell is *E. coli*, *S. cerevisiae*, *P. pastoris*, *D. melanogaster*, CHO-K1, CHOdhfr-, NS0, SP2/0, HEK 293, COS-1, COS-7, Percy 6, Namalwa or K562.

39. The host cell according to claim 37, **characterized in that** the host cell is an effector cell.
40. An organism comprising at least one host cell according to claims 34 to 38.
41. The organism according to claim 40, **characterized in that** the organism is a vegetable or an animal transgenic organism.
42. A composition comprising
 - (i) at least one recognition molecule according to any of claims 1 to 26,
 - (ii) at least one construct according to any of claims 27 to 29 and/or
 - (iii) at least one nucleic acid molecule according to claim 30 or 31.
43. The composition according to claim 42, **characterized in that** the composition is a pharmaceutical composition, optionally with a pharmaceutically tolerable carrier.
44. The composition according to any of claims 42 or 43, **characterized in that** the recognition molecule comprises:
 - (i) a radiolabelled recognition molecule according to any of claims 1 to 26 and/or
 - (ii) a non-labelled recognition molecule according to any of claims 1 to 26.
45. The composition according to claim 44, **characterized in that** the recognition molecule comprises a recognition molecule according to claim 26.
46. The composition according to claim 42, **characterized in that** the composition is a vaccine composition.

47. A method for the production of recognition molecules according to any of claims 1 to 28, comprising:
 - (i) incorporating one or more nucleic acid molecules according to any of claims 30 or 31 and/or an expression cassette or a vector according to claim 32 in a virus according to claim 33 or in a host cell according to any of claims 34 to 39;
 - (ii) culturing the host cells or the virus under suitable conditions; and
 - (iii) obtaining the recognition molecule, the effector cell bearing the recognition molecule, or the virus specifically recognizing a core 1 antigen.
48. A method for the production of a composition according to any of claims 42 to 46, comprising a combination of a recognition molecule according to any of claims 1 to 26, a construct according to any of claims 27 to 29, a nucleic acid according to claim 30 or 31 and/or a vector according to claim 32, together with a pharmaceutically suitable carrier, a solution and/or an adjuvant.
49. The method according to claim 48, additionally comprising the step of formulating the composition in a pharmaceutically tolerable and/or effective form.
50. Use of a recognition molecule according to any of claims 1 to 26, a construct according to any of claims 27 to 29, a nucleic acid molecule according to claim 30 or 31, a vector according to claim 32, a virus according to claim 33, a host cell according to any of claims 34 to 39, an organism according to claim 40 or 41 and/or a composition according to any of claims 42 to 46 in the prophylaxis, prevention, diagnosis, reduc-

- tion, therapy, follow-up and/or aftercare of tumor diseases and/or metastases.
51. The use according to claim 50 in the prophylaxis, prevention, diagnosis, reduction, therapy, follow-up and/or aftercare of core 1-positive tumor diseases and/or metastases.
 52. The use according to claim 50 or 51 in the prophylaxis, prevention, diagnosis, reduction, therapy, follow-up and/or aftercare of carcinomas.
 53. The use according to claim 52 in the prophylaxis, prevention, diagnosis, reduction, therapy, follow-up and/or aftercare of mammary carcinomas, gastrointestinal tumors, including colon carcinomas, stomach carcinomas, pancreas carcinomas, colon cancer, small intestine cancer, ovarian carcinomas, cervical carcinomas, lung cancer, prostate cancer, renal cell carcinomas and/or liver metastases.
 54. The use according to any of claims 50 to 53 in the prophylaxis, prevention, diagnosis, reduction, therapy, follow-up and/or aftercare of metastasization.
 55. The use according to claim 54, wherein the recognition molecule is a non-labelled recognition molecule according to claim 26, which corresponds to an IgM or IgG or has been derived therefrom.
 56. The use according to any of claims 50 to 55, wherein the recognition molecule is a radiolabelled recognition molecule according to any of claims 1 to 26, or a construct according to any of claims 27 to 29.

57. The use according to claim 56, wherein the recognition molecules are multibodies.
58. The use according to claim 56, wherein the recognition molecule is a recognition molecule according to claim 26.
59. The use according to any of claims 50 to 58, wherein the recognition molecule is a non-labelled recognition molecule according to any of claims 1 to 26 or a construct according to any of claims 27 to 29 and a labelled recognition molecule according to any of claims 1 to 26 or a construct according to any of claims 27 to 29, and wherein both recognition molecules or constructs are combined.
60. The use according to claim 59, wherein the non-labelled recognition molecule is a recognition molecule according to claim 26.
61. The use according to claim 59, wherein the labelled recognition molecule is a recognition molecule according to claim 26.
62. A method for the production of a diagnostic agent, comprising the steps of claim 47 for the production of core 1-specific recognition molecules, and comprising the step of formulating the recognition molecules in a diagnostically suitable form.
63. The method according to claim 62, **characterized in that** the recognition molecules are biotinylated, fluorescence-labelled, radioactively labelled, directly labelled via enzyme linking and/or detected via a secondary, appropriately labelled antibody.

64. Use of any of the methods according to claim 62 or 63, wherein the recognition molecule is employed in the diagnosis of tumor diseases and/or metastases, in the prognosis of tumor diseases and/or in the follow-up of tumor diseases.
65. The use according to claim 64, wherein the tumor diseases and/or metastases involve the liver.
66. The use according to claim 64 and/or of the method according to claim 63 or 64 in the diagnosis of core 1 antigen-bearing tumors.
67. The use according to claim 66, wherein the tumors are mammary carcinomas, gastrointestinal tumors, including colon carcinomas, stomach carcinomas, pancreas carcinomas, colon cancer, small intestine cancer, ovarian carcinomas, cervical carcinomas, lung cancer, prostate cancer, renal cell carcinomas and/or liver metastases.
68. The use of any of the methods according to claim 62 or 63, wherein the recognition molecules are employed in a tissue rapid test for immunohistologic detection.
69. The use according to any of claims 64 to 67, wherein the recognition molecules are employed in a tissue rapid test for immunohistologic detection.
70. The use according to any of claims 64 to 69, wherein the recognition molecules are employed in a serologic test in a sandwich procedure.
71. The use according to any of claims 64 to 70, wherein the recognition molecules are employed in *in vivo* diagnostics in the form of radioimmunodiagnostics, PET scan methods and/or immunofluorescence endoscopy.

72. The use according to any of claims 64 to 71, further comprising at least one additional antibody against at least one other tumor antigen and/or against at least one carrier molecule of said core 1 antigen.
73. A kit comprising a recognition molecule according to any of claims 1 to 26 and/or a construct according to any of claims 27 to 29.